

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: WAVE 3 CASES	

**RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO STRIKE
DR. SHELBY F. THAMES' SUPPLEMENTAL REPORTS OR, IN THE
ALTERNATIVE, FOR LEAVE TO FILE A *DAUBERT* MOTION**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this response to Plaintiffs' Motion to Strike Dr. Shelby F. Thames' Supplemental Reports or, in the alternative, for Leave to File a *Daubert* Motion Based on the Flawed Methodology Employed Therein ("Motion"). *See* [ECF No. 2883 ("Mot.")]. This Response applies to the cases identified in Exhibit A to Plaintiffs' Motion.

INTRODUCTION

Ethicon timely disclosed Dr. Thames as a general expert, and timely served on Plaintiffs Dr. Thames's initial expert report and the "Intentional Oxidation of Prolene Mesh Supplemental Report of Dr. Shelby F. Thames" ("First Supplemental Report"), both dated August 8, 2016. *See* Mot. Ex. B [ECF No. 2883-2]; Mot. Ex. C [ECF No. 2883-3]; *see also* Mot. at n.1 [ECF No. 2883].

As Dr. Thames explained in his First Supplemental Report, Plaintiffs have argued "that the explant cleaning protocol . . . use[d] during the examination of explant samples" as described

in his initial expert report “in some way, ‘destroys oxidation carbonyls’ should they exist.” Mot. Ex. C at 1. Plaintiffs first raised this argument—without any scientific support—in their Wave 1 *Daubert* briefing. *See* Mem. in Supp. of Pls.’ Mot. to Exclude Certain Opinions of Dr. Shelby Thames, at 8-10 [ECF 2042].

In response to Plaintiffs’ speculative assertions, Dr. Thames developed a test of his cleaning protocol “[t]o prove unequivocally this does not occur.” Mot. Ex. C at 1. Specifically, Dr. Thames tested his cleaning protocol by “intentionally oxidiz[ing] via exposure to ultraviolet light” “an exemplar Prolene mesh” for 500 hours. *Id.* Dr. Thames then processed the oxidized Prolene mesh using steps from his cleaning protocol, and evaluated it to determine if the process removed oxidation carbonyls. *Id.* at 12.

Although Dr. Thames had not completed his testing when Ethicon served his initial expert report and First Supplemental Report, he expressly stated in the First Supplemental Report that “[t]he oxidized Prolene exemplar [was] currently being processed through the cleaning steps of Figure 1, and that data will be reported when complete.” *Id.* On September 28, 2016, Ethicon served Dr. Thames’s Second Supplemental Report providing the completed data set to Plaintiffs. *See* Mot. Ex. D, “Intentional Oxidation of Prolene Mesh – Part 2, Supplemental Report of Dr. Shelby F. Thames,” (Sept. 28, 2016) [ECF No. 2883-4],

Plaintiffs now ask the Court to strike Dr. Thames’s Second Supplemental Report on the grounds that it was untimely served. *See generally* Motion. The Court should deny Plaintiffs’ Motion because the disclosure of Dr. Thames’s Second Supplemental Report is justified, and in an event, harmless to Plaintiffs in this litigation.

ARGUMENT

A. The Court Should Deny Plaintiffs' Motion To Strike Dr. Thames's Second Supplemental Report.

Federal Rule of Civil Procedure 37(c) provides that “[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.” In determining whether to exclude an expert’s supplemental report pursuant to Rule 37, this Court has consistently applied the five-factor test articulated by the Fourth Circuit in *Hoyle v. Freightliner, LLC*, 650 F.3d 321 (4th Cir. 2011). *See, e.g., Baugher v. Ethicon, Inc., et al.*, No. 2:12-cv-01053, 2016 WL 5871002, at *1 (S.D. W. Va. Oct. 6, 2016) (providing defendants additional time to depose plaintiffs’ expert based on a late-disclosed report); *Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *19 (S.D. W. Va. May 5, 2015) (declining to exclude amended report of Plaintiffs’ expert). Per *Hoyle*, a court should consider the following factors in determining whether to sanction a party under Rule 37(c):

(1) the surprise to the party against whom the witness was to have testified; (2) the ability of the party to cure that surprise; (3) the extent to which allowing the testimony would disrupt the trial; (4) the explanation for the party’s failure to name the witness before trial; and (5) the importance of the testimony.

650 F.3d at 329.

As discussed below, there is no basis for striking Dr. Thames’s Second Supplemental Report in this litigation under *Hoyle* because it did not “surprise” Plaintiffs, the opinions are important to Ethicon’s ability to defend against Plaintiffs’ claims, and no trial dates have been set in this litigation. Therefore, any harm that may have been done to Plaintiffs “may be easily

remedied by allowing them to have additional time to depose” Dr. Thames and allow for supplemental *Daubert* briefing. *Baughner*, 2016 WL 5871002, at *2.

A. Exclusion of Dr. Thames’s Second Supplemental Report is not warranted under the *Hoyle* test.

Application of the *Hoyle* factors demonstrates that the Court should deny Plaintiffs’ motion to strike Dr. Thames’s Second Supplemental Report. First, Dr. Thames’s Second Supplemental Report was no surprise to Plaintiffs. In his First Supplemental Report, Dr. Thames expressly stated that he would report the data from his testing upon completion. Mot. Ex. C at 12. Thus, it cannot be said that Dr. Thames’s Second Supplemental Report was a surprise to Plaintiffs, and Plaintiffs make no such argument here. Similarly, because there was no surprise, and therefore nothing to cure, the second factor also weighs against exclusion.

Turning to the third factor, there are no trial dates set for any of the Wave 3 cases identified in Exhibit A to Plaintiffs’ Motion. Thus, Dr. Thames’s testimony based on this testing does not present any risk of disrupting any trial.

As to the fourth factor, Ethicon notes that Dr. Thames performed the testing reported in his Second Supplemental Report to rebut Plaintiffs’ arguments first articulated in their Wave 1 challenge to Dr. Thames’s opinions. *See* Mem. in Supp. of Pls.’ Mot. to Exclude Certain Opinions of Dr. Shelby Thames, at 8-10 [ECF 2042]. Although this testing was not yet complete at the time Ethicon served his initial expert report and First Supplemental Report, Ethicon served Dr. Thames’s Second Supplemental Report as soon as Dr. Thames completed his testing and compiled the data.

Finally, with respect to the fifth factor, while the opinions contained in the Second Supplemental Report are not substantially different from those contained in his initial expert report or First Supplemental Report, they are important to Ethicon’s defense against Plaintiffs’

claims. As discussed in detail in Dr. Thames's initial expert report, Dr. Thames's testing of numerous mesh explants provides reliable and repeatable scientific evidence rebutting Plaintiffs' allegations that the Prolene in Ethicon mesh products oxidizes and degrades *in vivo*. See Mot. Ex. B, at 103-22. In response to this compelling testing, Plaintiffs claimed—without any scientific support—that Dr. Thames's cleaning protocol eliminates evidence of oxidation. Thus, the testing described in both of Dr. Thames's supplemental reports is significant in that it disproves Plaintiffs' speculation regarding the validity of his underlying test results.

Thus, Dr. Thames's testing is a proper rebuttal to Plaintiffs' assertions, which Plaintiffs certainly should have anticipated. In other words, Dr. Thames's Second Supplemental Report was not the result of inadequate or incomplete preparation, but rather a good-faith attempt to rebut Plaintiffs' challenges to the opinions identified in his initial expert report.

B. Ethicon does not object to additional time to depose Dr. Thames regarding his Second Supplemental Report and supplemental *Daubert* briefing.

Any harm done to Plaintiffs by Dr. Thames's Second Supplemental Report “may be easily remedied by allowing them to have additional time to depose Dr. [Thames]” and setting a schedule for supplemental *Daubert* briefing limited to the Second Supplemental Report and opinions contained therein. *Baughner*, 2016 WL 5871002, at *2. Ethicon respectfully submits that this approach is appropriate under these circumstances.

The Court has previously taken this course of action even when an expert's supplemental report advanced wholly new opinions, entirely distinct from those disclosed earlier. *Id.* (“The supplemental report is twenty-two pages long, whereas the original report is merely three pages long. Also, the supplemental report recommends that the plaintiff's TVT-O device be removed, but the original report recommended that the device stay in place. Finally, the supplemental report documents a number of alleged symptoms the plaintiff suffers that were not offered in the

original report.”). The results here should be no different, particularly since Dr. Thames’s Second Supplemental Report merely presents the completed results of his test, and not any new opinions.¹

C. This Court’s previous exclusions of supplemental reports are distinguishable.

Although this Court has previously stricken or excluded supplemental expert reports pursuant to Rule 37(c), those cases involved the disclosure of new opinions in cases approaching a trial date. For example, Plaintiffs point the Court to its decision to exclude Dr. Rosenzweig’s fourth supplemental expert report in *Huskey v. Ethicon*. See Mot. at 2. However, the Court’s ruling in *Huskey* was made at a pretrial conference with a trial looming. Indeed, the Court clearly explained that it excluded Dr. Rosenzweig’s supplemental report because it contained new opinions disclosed on the eve of trial. See Mot. Ex. E at 4:21-5:6 [ECF No. 2883-5].

No such circumstances exist with respect to Dr. Thames’s Second Supplemental Report, and the Court’s decision in *Huskey* is therefore inapposite. Accordingly, the Court should deny Plaintiffs’ motion.

CONCLUSION

For these reasons, the Court should deny Plaintiffs’ Motion to Strike Dr. Shelby F. Thames’ Supplemental Report.

¹ Plaintiffs argue that Dr. Thames’s testing is irrelevant and unreliable in this litigation. Mot. at 4. Although Plaintiffs’ arguments are meritless, Ethicon agrees that any such arguments should be addressed through supplemental *Daubert* briefing.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 20, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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